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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,723	06/20/2001	Balasulojini Karunanandaa	MTC 6783.1	3330

321 7590 10/02/2002

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,723	KARUNANANDAA ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in-condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1638

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I-VI. Claims 1-35, 38, 40, 42, 63-68, drawn to constructs, method of transformation, transformed cells, transgenic plants, classified in class 800, subclass 298, for example.

Group I -- HMGR and squalene epoxidase

Group II -- HMGR and sterol methyl transferase I

Group III -- HMGR and sterol C4-demethylase

Group IV -- HMGR and obtusifoliol C14-demethylase

Group V -- sterol C5-desaturase

Group VI -- methyl transferase II
 - VII. Claims 36, 37, 39-42, 76 and 77, drawn to method of breeding and hybride plants, classified in class 800, subclass 260, for example.
 - VIII. Claims 43-46, 49-51, 73, and 75, drawn to oil, classified in class 426, subclass 601, for example.
 - IX. Claims 47 and 48, drawn to sitosterol ester, classified in class 514, subclass 506, for example.

Art Unit: 1638

- X. Claims 52 and 53, drawn to method of lowering LDL cholesterol, classified in class 426, subclass 601, for example.
- XI. Claim 54, drawn to method of making a food additive, classified in class 426, subclass 601, for example.
- XII. Claims 55-62, drawn to DNA, classified in class 536, subclass 26.2, for example.
- XIII-XVIII. Claims 63-72, and 74, drawn to method of transformation, transformed host cell, transgenic plant, classified in class 800, subclass 278, for example.

Group XIII -- HMGR, squalene epoxidase, tocopherol synthase enzyme

Group XIV -- HMGR, sterol methyl transferase I, tocopherol synthase enzyme

Group XV -- HMGR, sterol C4-demethylase, tocopherol synthase enzyme

Group XVI -- HMGR, obtusifolioside C14-demethylase, tocopherol synthase enzyme

Group XVII -- HMGR, sterol C5-desaturase, tocopherol synthase enzyme

Group XVIII -- HMGR, methyl transferase II, tocopherol synthase enzyme

Claims 40 and 42 are generic to Groups I-VI and VII, and will be examined to the extent that they read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI, VII, X, XI, and XIII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

Art Unit: 1638

instant case, the different methods have different starting materials, different method steps and different end products.

3. Inventions VIII, IX and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the oil of Group VIII, the sitosterol ester of Group IX and the DNA of Group XII differ in structure, composition and function.

4. Inventions VIII, IX and I-VII, X, XIII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the oil of Group VIII, the sitosterol ester of Group IX and the DNA of Group XII cannot be used in the methods of Groups I-VII, X, and XIII-XVIII.

5. Inventions XII and I-VI, VIII-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA of Group XII can be used in other methods than the transformation methods of Groups I-VI, and VIII-XVIII, such as in a method of hybridization.

Art Unit: 1638

6. Inventions XII and VII, X, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the DNA of Group XII cannot be used in the methods of Groups VII, X and XI.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and because the search required for one of the groups is not required for another, restriction for examination purposes as indicated is proper.

8. Upon election of Group XII, Applicant is additionally required to elect a single nucleic acid sequence. This requirement is not to be construed as a requirement for an election of species, since each of the nucleic acid sequences or amino acid sequences recited in alternative form is not a member of a single structurally and functionally related genus, but rather constitutes an independent and patentably distinct invention. Separate searches and considerations would be required for examination of each of the nucleic acid sequences or amino acid sequences.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1638

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM.

The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 305-2272.



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Russell Kallis, Ph.D.

October 1, 2002